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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,663	02/06/2002	Chuan Li		9010

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11/16/2005

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,663	LI, CHUAN	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1743

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claims 21-38 recite that the amounts of the different polypeptides in the protein standard "represent different amounts of a known protein". The specification, as originally filed, does not provide sufficient description of what this recitation means. Examples 1-3 in the specification do not sufficiently describe how the amounts of the polypeptides in the protein standard "represent different amounts of a known protein" since these examples only state that the polypeptides in the protein standard are run on a SDS gel using bovine serum albumin (BSA) as a standard. Are the unknown amounts of the different polypeptides in the protein standard run in separate lanes on the gel with different known amounts of BSA in separate lanes, for example with 10 micrograms BSA in one lane of the gel, 5 micrograms BSA in another lane, and then 2 micrograms BSA in another lane? Are the intensities of staining in each of the lanes on the gel compared to one another so as to compare the staining obtained with each of the different polypeptides of the protein standard with the staining obtained with each of the different known amounts of BSA? It is not clear how the amounts of each of the different polypeptides in the protein standard are expressed. Are the amounts of the polypeptides expressed as an equivalent amount of BSA? In other words, would 10 micrograms of ovalbumin in the protein standard of

Art Unit: 1743

example 1 in the specification be expressed as 5 micrograms of BSA since both these amounts have the same staining intensity on the SDS gel? Further explanation of the meaning of the added limitation in the claims concerning "the amounts of polypeptides represent different amounts of a known protein" is needed than has been provided in the original specification.

Claims 22 and 30 contain new matter that is not supported by the specification as originally filed. Both claims 22 and 30 recite that the known protein whose amount the amounts of the polypeptides in the protein standard represent can be IgG. However, nowhere in the original specification is IgG described as being one of the known proteins used as a quantity standard protein. The specification only teaches of using bovine serum albumin (BSA) and lysozyme as standard proteins in protein assays for estimating the mass or amount of each polypeptide in the protein standard.

3. Claims 21-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Part d) of claim 21 is indefinite and unclear for the same reasons as given above in paragraph no. 2. See this same problem in part (b) of claim 29.

Regarding claim 22, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). See this same problem in claim 30.

On line 2 of claim 25, the phrase "at least one container means contains the protein standard according to" does not make proper sense and should be changed to --at least one container means containing the protein standard according to--.

Art Unit: 1743

On line 2 of claim 26, the phrase “the polypeptide in a protein sample” lacks antecedent basis.

Claim 32 is indefinite since the “detection assay of using the protein standard” has not been positively recited in independent claim 29, from which claim 32 depends. Claim 32 cannot refer back to claim 26 that recites a method of using a protein standard since claim 32 does not depend from this claim, and neither does independent claim 29.

4. Applicant's arguments filed October 24, 2005 have been fully considered but they are not fully persuasive.

The previous objection to claim 11 and the previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on July 26, 2005 have been withdrawn in view of the cancellation of these claims. New rejections of new claims 21-38 under both 35 USC 112, first and second paragraphs are set forth above, as necessitated by the introduction of the claims containing new limitations.

Applicant's arguments concerning the previous rejections of the claims under 35 USC 103 are persuasive, and therefore, these rejections have been withdrawn. However, as noted above, claims 21-38 do not currently recite the novelty of the invention as argued since these claims are unclear and not sufficiently described by the original specification.

Art Unit: 1743

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

November 14, 2005

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~180~~ 1700